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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/690,184	FOSTER ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 February 2007 and 25 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14,16,17 and 23* is/are pending in the application.

4a) Of the above claim(s) *23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14,16 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-12-2007 has been entered.

The amendment filed on 5-25-2007 is acknowledged. Claim 1 has been amended. Claims 1-9 and 18-22 have been canceled. Claim 23 has been added.

Election/Restrictions

Newly submitted claim 23 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the instant claims are drawn to methods of treating or preventing an *S. epidermidis* infection utilizing an antibody that binds to amino acids 51-598 of SEQ ID NO:10 whereas newly added claim 23 is drawn to a method of inhibiting *S. epidermidis* binding to a host cell, medical device or polymeric biomaterial.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 23 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 14 and 16-17 are currently under examination.

Declaration

The Declaration by Joseph M. Patti, PhD under 37 C.F.R. 1.132 filed on 2-12-2007 is acknowledged and has been fully considered.

Claim Objections Withdrawn

The objection to claim 17 for containing the obvious typographical error "Inhbiti" is withdrawn in light of the amendment thereto.

New Claim Objections

Claim 14 is objected to for using an abbreviation for a genus name without defining said abbreviation upon its first recitation. Appropriate correction is required.

Claim Rejections Withdrawn

The new matter rejection of claims 14 and 16-17 under 35 U.S.C. 112, first paragraph, based on the claim 14 limitation "to amino acids 51-598 of SEQ ID NO:10" is withdrawn in light of Applicant's arguments.

The new matter rejection of claim 16 17 under 35 U.S.C. 112, first paragraph, based on the limitation "encoded by a nucleic acid having the sequence of nucleotides 151-1794 in SEQ ID NO:7" is withdrawn in light of Applicant's arguments.

Claim Rejections Maintained

35 USC § 112, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 14 and 16-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained essentially for the reasons set forth in the previous Office action. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant argues:

1. Since Applicant's have disclosed a specific antigen, they have met the requirements for written description as set forth in Example 16 of The Written Description Guidelines.

2. The only relevant consideration is whether the original application provides a suitable written description clearly enough that one having ordinary skill in the pertinent art would recognize from the disclosure that the patentee invented processes including the claim limitations.

3. The fact that the Applicants disclose an antibody to a specific, well-characterized antigen clearly indicates no further description or analysis of the question of epitopes or immunoepitopes is necessary. One skilled in the art would readily be able to generate antibodies to the specific antigen of the claims and be able to use said antibodies to do exactly what they are claimed to do.

4. Since polyclonal antibodies by nature target multiple epitopes there is no need or relevance to identify specific epitopes or immunoepitopes.

5. Description of the target of the claimed antibodies, A domain of SdrG, is sufficient for one to make and use the invention (as evidenced by the Patti declaration).

6. The application describes repeatedly the use of the antibodies of the present invention in the treatment and prevention of infection from *Staphylococcus epidermidis* the meeting the requirements set forth in the Written Description Training materials.

7. The instant claims are now drawn to treating infection by *Staphylococcus epidermidis* not all coagulase-negative staphylococcal infections by using antibodies to a specific antigen (i.e. amino acids 51-548 of SEQ ID NO:10).

Applicant's arguments have been fully considered and deemed non-persuasive.

The rejected claims are drawn to methods of utilizing antibodies that bind to a fragment of the *Staphylococcus epidermidis* SdrG protein (i.e. amino acid residues 51-598 of SEQ ID NO:10 encoded by nucleic acid residues 151-1794 of SEQ ID NO:7) to treat or prevent *Staphylococcus epidermidis* by their administration to a subject.

With regard to Points 1 and 3, Applicant is correct that the specification meets the written description requirement with regard to antibodies that bind the SdrG protein. However, the instant claims, as amended, require the claimed antibodies not only be able to bind the recited portion of SdrG, but they must also elicit a therapeutic or prophylactic immune response to *Staphylococcus epidermidis*. Since the specification does not adequately describe antibodies with both properties, the specification does not meet the written description requirement with regard to antibodies that **both** bind to the recited portion of SdrG **and** elicit a prophylactic immune

response to *Staphylococcus epidermidis* (see below).

With regard to Point 2 and 3, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

With regard to Point 4, the instant claims are not limited to the use of polyclonal antibodies. Consequently, Applicant's argument is not germane to the full scope of the claims.

With regard to Point 5, the ability to "make and use" an invention is an enablement issue not a written description issue. Moreover, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Additionally, The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Finally, the Declaration by Dr. Patti is not persuasive as the compositions used are not commensurate in scope with those of the instant invention.

With regard to Point 6, the specification failed to disclose any antibody capable of preventing *Staphylococcus epidermidis* infection. The specification prophetically discusses the use of antibodies to "protect" but fails to disclose any antibody that is able to induce a protective immune response. It should be noted that "passive immunity" is not the same as protective

immunity as the former lasts only as long as the administered antibody is present while the latter endures long after the administered "vaccine" has been catabolized.

With regard to Point 7, the amendment to the claims, as evidenced by this rejection, is not sufficient to overcome this rejection.

As outlined previously, the claims encompass, in part, a vast genus of antibodies that are capable of binding to the recited portions of the *Staphylococcus epidermidis* SdrG protein. Within this large genus, the claims further encompass a subgenus of antibodies that must have efficacy to treat or prevent *Staphylococcus epidermidis* infections by inhibiting fibrinogen binding. There is no basis in the specification, as filed, or the art at the time of the invention to distinguish the members of this subgenus from the members of the larger genus.

To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of antibodies that are encompassed by the rejected claims one must describe not just those determinants that would elicit an immune response to the SdrG polypeptide (i.e. that produce antibodies that bind to the claimed SdrG fragment) but which determinants would give rise to antibodies that would have therapeutic and/or prophylactic efficacy against *Staphylococcus epidermidis* infections

since a given determinant can induce antibodies that bind to the SdrG fragment but lack any therapeutic and/or prophylactic efficacy.

The specification does not describe with any degree of specificity a single member of the genus of epitopes of SdrG to which the members of the claimed genus of antibodies must bind, wherein said antibodies can effectively treat or prevent *Staphylococcus epidermidis* infections by inhibiting fibronectin binding such that the specification might reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

Moreover, the specification does not disclose distinguishing and identifying features of a representative number of members of the genus of antibodies to which the claims are drawn, such as a correlation between the structure of the immunoepitope its recited function (to induce/bind antibodies with therapeutic and/or prophylactic efficacy against coagulase-negative staphylococcal infections), so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of antibodies. Additionally, the specification fails to disclose which amino acid residues are essential to the function of the immunoepitope or which amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent, or by which other amino acids the essential amino acids might be replaced so that the resultant immunoepitope retains the activity of its parent. Therefore, since the specification fails to adequately describe at least a substantial number of members of the genus of immunoepitopes on which the claims are based; the specification fails to adequately describe at least a substantial number of members of the claimed genus of antibodies that bind to the claimed *Staphylococcus epidermidis* SdrG fragments **and** have therapeutic and/or

prophylactic efficacy against *Staphylococcus epidermidis* infections by inhibiting fibronectin binding.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient

description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Greenspan et al. (*Nature Biotechnology* 7: 936-937, 1999), defining epitopes is not as easy as it seems. Greenspan et al. recommends defining an epitope by the structural characterization of the molecular interface between the antigen and the antibody is necessary to define an "epitope" (page 937, column 2). According to Greenspan et al., an epitope will include residues that make contacts with a ligand, here the antibody, but are energetically neutral, or even destabilizing to binding. Furthermore, an epitope will not include any residue not contacted by the antibody, even though substitution of such a residue might profoundly affect binding. Accordingly, it follows that the immunoepitopes that can elicit a protective immune response to a given pathogen can only be identified empirically. Therefore, absent a detailed and particular description of a representative number, or at least a substantial

number of the members of the genus of immunoepitopes, the skilled artisan could not immediately recognize or distinguish members of the claimed genus antibodies that bind to the *Staphylococcus epidermidis* SdrG protein and have therapeutic and/or prophylactic efficacy against *Staphylococcus epidermidis* infections. Therefore, because the art is unpredictable, in accordance with the *Guidelines*, the description of immunoepitopes (antigenic determinants) is not deemed representative of the genus of antibodies to which the claims refer.

Enablement

The rejection of claims 14 and 16-17 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained essentially for the reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues:

1. The key question with regard to enablement and undue experimentation is not whether a large amount of experimentation is necessary to achieve the goals of the invention but whether the nature of the experimentation is routine.

2. The instant specification precisely discloses how to make antibodies to the A domain of SdrG and describe in detail that the antibodies could be used to block *Staphylococcus epidermidis* adhesion and treat *Staphylococcus epidermidis* infection.

3. The Examiner recognized that practitioners have been able to make and use the claimed invention but merely contested the manner of providing this information not being in the form of

a Declaration.

4. As set forth in the Patti declaration, scientists have been able to generate antibodies in accordance with the teachings of the instant invention and administer those antibodies to achieve the desired results of reducing or treating *Staphylococcus epidermidis* infections. As set forth in the declaration, experimental testing in both pre-clinical and clinical setting has demonstrated that antibodies capable of binding to SdrG are capable of treating and preventing staphylococcal infections as evidenced by the "Update of Veronate". Moreover, Another inventive group studying antibodies to protein Fbe (asserted to be equivalent to SdrG) found that those antibodies could be used to treat or prevent infection by *S. epidermidis.*

5. Studies have shown that the SdrG portion of an antibody composition was necessary to provide protection *in vivo.*

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to Point 1, the experimentation required to make an antibody with efficacy as a prophylactic against *Staphylococcus epidermidis* infection would not be routine as no such antibody is known to exist. In the art of immunology, the only antibodies that are known to be capable of inducing a protective response against a pathogen are those antibodies that mimic antigens from said pathogen (i.e. anti-idiotypic antibodies). The teachings of the instant specification are limited to the production of antisera using the A domain of SdrG as an immunogen. Any "protective antibodies" elicited by the administration the anti-SdrG antibodies of the instant invention would be specific for those anti-SdrG antibodies not *Staphylococcus epidermidis.* It should be noted that "passive immunity" is not the same as protective immunity

as the former lasts only as long as the administered antibody is present while the latter endures long after the administered "vaccine" has been catabolized.

With regard to Point 2, the instant claims require that the claimed antibodies be able to induce a protective immune response against *Staphylococcus epidermidis* infections not merely treat said infections.

With regard to Point 3, contrary to Applicant's assertion, the Examiner set forth the deficiencies of the data set forth in Appendix II (which is no incorporated into the Patti declaration).

With regard to Points 4 and 5, the cited portions of the specification are do not disclose (i.e. demonstrate) that antibodies to the claimed fragments of the SdrG protein have efficacy in the prevention of *Staphylococcus epidermidis* infection. Said portions of the specification merely prophetically refer to the use of the SdrG protein or "portions thereof" in treatment/prevention methods. The rejected claims are drawn to the prophylactic use of antibodies that bind to fragments of the SdrG protein. To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed use of the claimed antibodies provide any sort of protective immunity in any accepted model system. Applicant discloses that the antibodies to SdrG or fragments thereof "can be used to impart passive immunity, are useful for the specific detection of coagulase-negative staphylococci proteins, for the prevention a coagulase-negative infection, for the treatment of an ongoing infection or for use as research tools" (see page 28 of specification) in a prophetic sense but fails to demonstrate said immunity/treatment in any animal system. While the skill in the art of immunology is high,

to date, prediction of protective immunity (in this case passive immunity) for any given composition in any given animal is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective immunity, the specification, as filed, does not provide enablement for methods of inducing immunity (passive immunity) to coagulase-negative streptococci in any animal (including man), comprising administering to said animals an antibody that binds to the recited fragments of the SdrG protein.

Additionally, as set forth in the last office action, the "evidence" presented in Patti declaration (Appendix II) is not commensurate in scope with the claimed invention. The instant claims are drawn to prophylactic/therapeutic methods utilizing antibodies that bind to specific fragments of the SdrG protein whereas the "data" presented in said Appendix is drawn to the use of Veronate® (a plasma derived, donor-selected polyclonal IVIG of unknown composition). And the instant claims are not limited to polyclonal antibodies. Moreover, one cannot determine whether the Veronate® composition contained antibodies that would bind to the recited fragments of the SdrG protein or whether the disclosed "immunological effects" of the Veronate® composition could be ascribed to antibodies that would bind to the recited fragments of the SdrG protein (if present). The MPEP states:

716.01(b) Nexus Requirement and Evidence of Nonobviousness
TO BE OF PROBATIVE VALUE, ANY SECONDARY EVIDENCE MUST BE RELATED TO THE CLAIMED INVENTION (NEXUS REQUIRED)
The weight attached to evidence of secondary considerations by the examiner will depend upon its relevance to the issue of obviousness and the amount and nature of the evidence. Note the great reliance apparently placed on this type of evidence by the Supreme Court in upholding the patent in *United States v. Adams*, 383 U.S. 39,148 USPQ 479 (1966).
To be given substantial weight in the determination of obviousness or nonobviousness, evidence of secondary considerations must be relevant to the subject matter as claimed, and therefore the examiner must determine whether there is a nexus between the merits of the claimed invention and the evidence of secondary considerations. *Ashland Oil, Inc. v.*

Delta Resins & Refractories, Inc., 776 F.2d 281, 305 n.42, 227 USPQ 657, 673-674 n. 42 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986). The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), *cert. denied*, 488 U.S. 956 (1988).

The data presented in the aforementioned declaration does not provide said nexus and hence has no probative value.

Finally, with regard to the Rennermalm article, there is no nexus between the cited art and the instant claims as the proteins used to generate the antibodies are different and hence would contain differing immunoepitopes and would generate differing immune response. Moreover, contrary to Applicant's assertion, the cited reference does not disclose that antibodies to Fbe are effective in treating and/or preventing infection by *S. epidermidis*, said reference discloses that the Fbe protein itself is a "strong candidate for continued development of antibody-mediated therapy of prophylaxis against infection" (see page 3083). The cited reference provided no data as to the *in vivo* efficacy of antibodies to the Fbe protein. The only *in vivo* data involved the *ex vivo* opsinization of bacteria with sera prior to its injection into the test animal. The resulting data, sheds no light of the *in vivo* efficacy of antibodies to Fbe in treating established infections or preventing the development of infections. It should be noted that the cited reference only deals with a single staphylococcal species (*S. epidermidis*) while the instant claims encompass all coagulase-negative staphylococci.

As outlined previously, the specification contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention without undue experimentation.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include, but are not limited to:

1. The breadth of the claims,
2. The nature of the invention,
3. The state of the prior art,
4. The level of one of ordinary skill,
5. The level of predictability in the art,
6. The amount of direction provided by the inventor,
7. The existence of working examples, and
8. The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

Said factors as they apply to the instant claims are addressed below.

Breadth of the claims

The rejected claims are drawn to the prophylactic or therapeutic use of antibodies that bind to the recited fragments of the *Staphylococcus epidermidis* SdrG polypeptide wherein said antibodies inhibit fibrinogen binding.

Working Examples/Guidance of Specification

The specification provides no working examples demonstrating the efficacy of claimed methods. The working examples are limited to methods of identifying Sdr genes, expression of said genes and the sequencing of

the resulting Sdr gene products. The specification is silent with respect to the use of specific anti-SdrG antibodies for the treatment or prevention of *Staphylococcus epidermidis* infections.

State of the prior art and Unpredictability of the art

To be a prophylactic composition, the composition must elicit protective immunity, demonstrable by pathogen challenge experiments in a reasonable model system. The specification, as filed, does not set forth that the claimed use of the claimed antibodies provide any sort of protective immunity in any model system that can be extrapolated to humans or any other mammal. Applicant states that the claimed antibodies "... are useful as blocking agents to prevent or inhibit the binding of coagulase-negative staphylococci." in a prophetic sense but fails to demonstrate any therapeutic or prophylactic efficacy in any animal system. The specification is silent as to which polynucleotide/host/microorganism would be effective to prevent a given condition associated with infection by *Staphylococcus epidermidis*. The examples, disclosed in the instant specification, are limited to the identification Sdr genes, expression of said genes and the sequencing of the resulting Sdr gene products. While the skill in the art of immunology is high, to date, prediction of protective immunity for any given composition in any given animal is quite unpredictable. Given the lack of success in the art, the lack of working examples and the unpredictability of the generation of protective immunity, the specification, as filed, does not provide enablement for methods of preventing *Staphylococcus epidermidis* infections, comprising administering to a patient antibodies to the *Staphylococci epidermidis* SdrG protein. Additionally, the specification provides no guidance as to what antibodies would be "therapeutic" for a *Staphylococcus epidermidis* infection. To be a treatment composition, said composition must provide a benefit to the subject to which it is administered. The specification,

as filed, does not set forth which "antibody", if any, would provide a benefit when administered within the context of a coagulase-negative staphylococcal infection. While the skill in the arts of medicine, pharmacology and immunology is high, to date, prediction of therapeutic efficacy for any given composition is quite unpredictable. Consequently, one of skill in the art would not be able to contemplate which "antibody" would be an effective "treatment" for a *Staphylococcus epidermidis* infection. Given the lack of success in the art, the lack of working examples and the unpredictability of therapeutic efficacy, the specification, as filed, does not provide enablement for methods of treating coagulase-negative staphylococcal infection, comprising administering an antibody that binds to the *Staphylococci epidermidis* SdrG protein.

New Grounds of Rejection

35 USC § 102

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Upon careful review of the record, the rejection of claims 14 and 16-17 under 35 U.S.C. 102(e) as being anticipated by Douchette-Stamm et al. (U.S. Patent 6,380,370 – IDS) is reinstated.

As outlined previously, Douchette-Stamm et al. disclose a polypeptide from *Staphylococcus epidermidis* (see SEQ ID NO:5314) with 99.9% sequence homology to the SdrG protein of the instant application (SEQ ID NO:10). Douchette-Stamm et al. further disclose antibodies that specifically bind to said polypeptide (see column 9, lines 8-22). Finally,

Douchette-Stamm et al. disclose the use of said antibodies in methods "...for preventing or treating disease caused by certain bacteria", including *S. epidermidis*..." (i.e. bacterial infection)[see column 10, lines 42-50]. The amended claims, however, require that said antibodies bind to a specific portion of the SdrG protein (i.e. amino acid residues 51-598 of SEQ ID NO:10 which is encoded by nucleic acid residues 151-1794 of SEQ ID NO:7). It is deemed, in the absence of evidence to the contrary, that the antibodies disclosed by Douchette-Stamm et al.. would necessarily bind to the claimed amino acid sequences especially given that Douchette-Stramm et al. disclose both monoclonal and polyclonal antibodies (see column 41, lines 9-10).

Since the Patent Office does not have the facilities for examining and comparing Applicant's composition with the compositions of the prior art reference, the burden is upon Applicant to show a distinction between the material, structural and functional characteristics of the claimed composition and the composition of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 recites the limitation "the ligand binding A region" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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ROBERT A. ZEMAN
PRIMARY EXAMINER

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